

CS
PRIVILEGED & CONFIDENTIAL

PHILIP MORRIS "WHITE PAPER" ON SMOKING AND HEALTH

2504099706



20200111057

C3

Philip Morris acknowledges that cigarette smoking is a risk factor for certain types of lung cancer and several other diseases, because a statistical association exists between smoking and the occurrence of those diseases. (1990 Annual Report, p. 3) PM uses the term "risk factor" to refer to a factor, behavior or other variable that has been statistically associated with a specific disease. In the case of lung cancer, statistical studies have reported that smokers develop the disease at a higher rate than non-smokers. A risk factor may or may not be causally related to the disease. In fact, it is a well-recognized and accepted scientific principle that statistics can never establish causation. As the authors of the 1964 Surgeon General's Report observed:

"Statistical methods cannot establish proof of a causal relationship in an association. The causal significance of an association is a matter of judgment which goes beyond any statement of statistical probability."
(p. 20)

2504099707

However, statistical associations have value in that they suggest avenues for further research and they raise questions about disease causation which can only be answered on the biological or mechanistic level.



To describe cigarette smoking as a risk factor is consistent with the current state of scientific knowledge. This description acknowledges that there is evidence from epidemiology and other disciplines that suggests that smoking may contribute to the production of some diseases, but it also recognizes the limitations of and the inconsistencies in that evidence. Consequently, the available scientific evidence does not rise to the level of establishing scientifically a causal relationship. In regard to lung cancer, for example, there are three facts that support this view. First, despite years of effort and considerable expense, no human-type lung cancer has been produced in experimental animals as a result of the inhalation of fresh tobacco smoke. Second, no constituent of tobacco smoke as found in the smoke has been shown to cause lung cancer. Third, no biological mechanism by which tobacco smoke might cause lung cancer has been demonstrated by science. As two separate groups of researchers observed recently:

"Although a large number of factors have been associated with the development of malignant neoplasms in humans, the mechanisms involved are still largely unknown."

(Albanes & Winick, JNCI, 7/20/88, p. 772)

2504099708



"Despite dramatic progress in the understanding of carcinogenesis, the critical genetic events and promotion factors required for malignant transformation remain unknown."

(Shaw & Srivastava, JNCI, 9/1/93, p. 1377)

2504099709

These are among the important questions that must be resolved before a causal relationship can be scientifically proven or rejected.

The complex nature of the diseases associated with cigarette smoking is further demonstrated by the fact that they are multifactorial in nature, meaning that many risk factors have been statistically associated with their development. The following are just a few of the conditions or behaviors, in addition to cigarette smoking, which have been associated with these diseases: dietary habits, family history and genetic make-up, age, occupational exposures, place of residence, personality types, socioeconomic class, and air pollution. These risk factors have been identified by the same kinds of epidemiological studies that have addressed cigarette smoking and health.

Philip Morris acknowledges that its views regarding smoking and health are often not regarded as credible. However, recent testimony by independent experts raises questions about



whether causation has been proven. For example, Dr. Walter L. Barker, a thoracic surgeon and Clinical Professor at the University of Illinois, testified in 1993 that he believes the case against cigarette smoking has not been proven. (Kueper v. R.J. Reynolds Tobacco Co., et al., January 21, 1993) In his testimony, Dr. Barker stated that the statistical case against cigarette smoking is flawed and that over the years he has noticed many anomalies in his own clinical practice. These include the following:

- (1) Lung cancer was on the rise before smoking became popular in the 1920's.
- (2) Cancer of the trachea is rare, even though the lining in that part of the respiratory system is the same as that of the major airways of the lung, and the trachea is constantly exposed to cigarette smoke in smokers.
- (3) The rate of laryngeal cancer has remained remarkably stable, even though it is composed of the same tissue as the lung and trachea.
- (4) The amount of tobacco smoke exposure (the "dose") does not affect the time when lung cancer is diagnosed. Lung cancer generally occurs between the ages of 50 and 70

2504099710

- 4 -



with a mean age of 60 years, regardless of when a person started smoking.

- (5) Fewer than 10 percent of smokers, including "heavy" smokers, develop lung cancer.
- (6) There are various demographic anomalies in the statistical data, including the fact that Japanese men smoke much more than American men, but have half the lung cancer rate.

Philip Morris believes that the risks associated with smoking are well-known to the public and that individuals should have the right to choose whether to smoke. We insist that the decision to smoke, like many other lifestyle decisions, should be made by informed adults.

2504099711

